# The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics Meeting March 10-11, 2003 – Meeting #5

# Day 1 – March 10, 2003

The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics convened on March 10, 2003, at the Pikesville Hilton in Pikesville, Maryland for its fifth meeting. Shortly after 9:00 a.m., Commissioners Lynn Sylvester and Ira Lobel with the Federal Mediation and Conciliation Services (FMCS) called the meeting to order. Ms. Sylvester informed the committee that member Leslie Lloyd from the American Occupational Therapy Association was not in attendance because of the pending arrival of her new baby. Julie Kass will serve as primary committee member in her place. Judy Thomas, Director of Reimbursement and Regulatory Policy, AOTA will be the new alternate committee member. Ms. Sylvester distributed the Sign-in Sheet (Attachment 5.1) and noted a request to reorder the sequence of items on the agenda (Attachment 5.2). As she reminded the committee that the agenda was a "rolling" agenda, she received no objections to reshuffling the items.

Mr. Lobel led the committee through a review of the minutes from the February 10-11, 2003, meeting. Noting minor corrections and a request to list each member's organization with their name when comments are first attributed to a person, the committee approved the minutes by consensus (Attachment 5.3 – Meeting #4 Minutes).

Before addressing the first item of business, Ms. Sylvester reviewed the order of agenda items. The brief presentations scheduled from the American Board of Certification (ABC), the Board for Orthotist/Prosthetist Certification (BOC), and the National Orthotic Manufacturers Association (NOMA) were moved behind the physical therapist (PT) and occupational therapist's (OT) presentations. NOMA representative Stuart Kurlander asked that his organization be exempt from making a presentation, stating that NOMA has not claimed it is qualified as a qualified practitioner under the statute and therefore will not make a presentation. Other members of the committee voiced opinions expressing their desire to hear a presentation from NOMA, if only to gain more information/knowledge about the organization. NOMA stated it would be receptive to answering any questions the group had. The committee agreed to move the presentations down on the agenda list and the group would re-visit the NOMA issue later.

The committee was informed that CMS Medical Officer, Dr. Laurie Fienberg would be unable to attend the meeting, but Joel Kaiser, CMS Health Insurance specialist would attend on the second day. Next, the committee immediately embarked on the task of discussing which prosthetics would be covered under the statue.

#### **Discussion on Inclusion of Prosthetics Covered under the Statute**

Many members of the committee felt the statute is only applicable to upper and lower limb prosthetics. They felt this range does not include items such as eyes, and breast protheses. CMS representative Hugh Hill explained to the group that CMS makes a distinction between "items of prosthetics" and "prosthetic devices." Items of prosthetics, he noted, included ocular implants. Prosthetic devices include things such as breast and penile implants (things they do not want to include under the statue). When asked, "do all prosthetic devices require a doctor's prescription?" Mr. Hill responded, "yes, normally." He went on to say it's an issue of liability and reimbursement. Comments from the committee on this issue included:

- If a supplier applies for reimbursement and does not have the level of training they need, they would be committing Medicare fraud.
- There are no such certifications they must abide by.
- The physician will make a diagnosis and write a prescription. However, the physician cannot make a recommendation to a specific orthotist/prosthetist (O/P). This would be unfair to the competition.
- In States where there is licensure, a prescription is required (there are 10 States).
- We should exclude the L5000 code because it involves shoe inserts and this is excluded from the statute.
- The committee should approve all items and then let CMS exclude items as it sees appropriate.

Dr. Hill stated that the CMS team could provide a definition for "items of prosthetic" and "prosthetic devise" by the lunch hour. However, if a list of codes was desired, that could not be available until the following day. There was a request that CMS consider permanent versus temporary prosthetics when generating its definition. Member John Michael from the American Orthotic and Prosthetic Association (AOPA) volunteered to provide a list of applicable codes based on the CMS definitions. After a few more minutes of discussion, the group agreed by consensus to the following preliminary prosthetic definition.

All external upper and lower (and torso) prostheses are covered by the statute. These include existing codes L5000 – L7520, L8400 – L8499, K0556 – K0559.

The group was informed that Joel Kaiser took a first pass at generating a list of applicable codes. The list was distributed to the committee for consideration (Attachment 5.4 – BIPA247 Codes). They agreed they would have to ask Joel the rational for putting some of the items on the list (e.g., L5400, L5410, L5420, L5430). The committee also questioned how it would exclude ocular implants if the code(s) is on the list. Dr. Hill said it was something they would have to think about.

After a short break, the committee agreed on the following preliminary definition:

Prostheses = artificial arms, legs, and eyes, including replacements, if required, because of a patient's physical condition –  $SSA \S 1861(s)$ . (It was noted that this is a coverage provision and should only be seen as a working definition.)

There was a suggestion that L5000 be kept on the list and criteria set for Certified Pedorthists to provide services. In response to this suggestion, the question "do Pedorthists provide ped. prosthetics?" The answer was, "there is overlap at the partial foot level and so it's a gray area." (At this time, Committee member Tony Barr, Barr Foundation, held up a device that was an artificial foot including the distal half of the foot and entire sole. It included a stirrup splint rising above the malleoli.)

CMS agreed to further refine the preliminary definition prior to the next meeting. After reviewing the list of codes provided by Joel Kaiser, NOMA withdrew its earlier proposal and noted its support of the CMS list of codes, considering it conclusive. Other members of the committee noted the CMS list did not reflect only base codes and others wanted an opportunity to review the list overnight. Other members voiced concern regarding immediate post-op and preparatory protheses being on the list. The committee agreed to preliminarily include, at a minimum, the CMS list (K0556 – L4020). It was noted that they could review the list overnight and should next consider,

- 1. Which L codes should not be included?
- 2. Which L codes should be added?

## **Qualified Provider**

After lunch, the committee addressed the issue of a "qualified provider." Both the PT and OT representatives provided the committee with various handouts to support their position:

Attachment 5.5 – PT package comprising qualified physical therapist definition, definition of qualified physical therapist statute and regulation citations, and qualifications of persons providing physical therapy services.

Attachment 5.6 – OT package comprising qualified occupational therapist definition, statutory definition of occupational therapy services, and list of statute and regulation citations.

Cathy Ellis from the American Physical Therapy Association reminded the committee that all PT work is done by physician referral and under physician prescription. She urged the committee to adopt the long-standing Medicare definition of a qualified physical therapist and noted the term is used at least 74 times in the Social Security Act, Medicare regulations, and program manuals.

Julie Kass from AOTA noted, that "instead of creating a separate set of statutory provision of occupational therapy, Congress enacted SSA 1861(g), which provides that the term physical therapy services will also mean occupational therapy services each place it appears in the law and regulations." Furthermore, she added, "qualified occupational therapist" is a term that was already part of the Medicare statute prior to passage of Section 427 of BIPA and a consistent definition of "qualified occupational therapist" has been expressed by CMS in its regulations, manuals, and other issuances. Finally, she acknowledged that CMS has also indicted that it plans to codify its current practice using the home health agency regulation definition of qualified occupational therapist as the sole definition in all contexts (67 Fed. Reg. 3641 – January 25, 2002). Following these comments the committee asked a series of questions:

- Q: If the proposed change in the home health regulation definition goes into effect, will it affect our decision?
- A: No, it would not make a difference in our deliberations.
- Q: How many States have specific scope of practice statues for P/O work?
- A: We would have to look at all State practice acts but I know many of them do (It's variable for PTs and OTs).
- A: Terry Supan offered that by virtue of licensure in 10 states for prosthetists and orthotists, the public is protected.
- Q: Are there any States that license OTs and PTs for fabrication?
- A: There are State scopes of practices that specifically say OTs can fabricate. We would have to look at each one separately for prosthetics and orthotics.
- Q: Is there anybody who is not a PT/OT that could claim to be so and provide services, e.g., a PT Technician?
- A: Our State practice acts are explicit regarding what we call ourselves. Medicare only pays for PT services provided by a PT. The KT (kinesio therapist) would more likely try to provide services under a P/O title.

The group continued to discuss this issue at length. Some members felt the language of the statute clearly includes qualified PTs/OTs as a qualified practitioner. Other members of the committee thought the issue was really one of competence and asserted that the scope of practice for PTs/OTs is governed by codes of ethics and expects that they are trained, therefore to be qualified by license doesn't mean they will do everything within the scope of practice. When comparing PT/OT work to P/O work, some committee members felt the O/P State practice acts are more uniform. Still other members felt both disciplines require professionals to practice within their scope of competence and it would be unethical for either group to do work outside of this, so both groups (PTs/OTS and O/P) should be treated the same way. Additional questions posed by the committee included:

Q: If I received an immediate post-op prosthesis in a hospital, it would matter to me who fit it to me and who fabricated it. Would you fabricate it (a PT)?

- A: A PT would not be forbidden to fabricate but they could choose not to do it. Keep in mind, there are Medicare participation guidelines in hospital settings as well. There are severe ramifications if personnel are not competent to perform services, as noted in their personnel file.
- Q: What do I want to have in the personnel file to demonstrate competency for postop care?
- A: CAAHP and JCAHCO have numerous standards. They will pull the chart and pull the personnel file and they will need to see specific competency for the area of practice.
- Q: What are they seeing?
- A: For example, for a frail elderly person, they want to see that all body systems impacted by the treatment are addressed in my competency before I did the intervention.
- Q: For post-op care, what is the measure of competency?
- A: Each service area in the hospital has a plan for clinical competency with timeliness (it's a *demonstrated* competency). An item gets checked off the list for each procedure. The plan is developed based on services being offered by the facility.
- Q: The statute says "qualified" not "licensed." So why can't a person give up their license and open an O/P practice?
- A: The statute says "qualified" means "licensed." So if you give up your license, you are no longer qualified. If you are operating in a State where there is no statute for doing O/P work, Medicare could not pay you for the services. The two terms (qualified and licensed) are essentially interchangeable.
- Q: Is it CMS' view that the two terms are interchangeable?
- A: We think legally that it could go either way.
- Q: JCAHCO applies to hospital-based practices, does it apply to private practice as well?
- A: The standards may not apply directly to private practice but license acts hold you to standards of your peers, so you would use same criteria. Specifically, the Department of Agriculture, Consumer Affairs Department would hear complaints from patients.

After the committee took a short break, member Kim Doolan, Barr Foundation, related information from the Council of Physical and Occupation Therapists in Texas and the Texas Board of Orthotics and Prosthetics on her inquire about how they handle infractions. She told the committee their response was they have so many complaints they didn't know when they would get to the O/P complaints. They stated they only have 3 examiners (for 12 state agencies) to investigate all the complaints regarding a variety of

matters, including complaints against massage therapists and physical therapists, but not necessarily related to O&P.

During the break, the facilitators generated the beginning of a definition for qualified PT/OT, which then lead to additional questions:

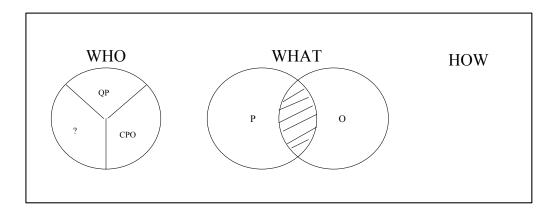
### Orthotics

- Licensed by State
- Acts within scope of practice
- Acts within scope of competence

Prosthetics = immediate post-op (in hospital, JCAHCO, deemed status for Medicare)

- Licensed by State
- Acts within scope of practice
- Acts within scope of competence (akin to privileging)
- Q: What is the connection in education that allows PT/OTs to do O/P work? Where is it covered in your training?
- A: We've already answered that question. Per the statute, we are qualified to provide certain custom fabricated orthotics.

In an attempt to move the discussion along, John Michael, AOPA, provided a conceptual illustration, below.



In response to the illustration, one member commented, "if you get the *who* then you automatically get the *what*." Other comments included:

- If we hold the discussion of L codes for later discussion then we need to take it off the working definition.
- If the statute says PT/OTs are qualified then what is the discussion about, it's not up for discussion.

- Why don't we look at PT/OT qualification by separating orthotic versus prosthetic discussions.
- The law is pretty clear, they are providers.

A vote was taken to determine if consensus could be reached on the statement "Qualified PT/OT means licensed by their State." Consensus could not be reached. When asked if the vote would change if the issues of prosthetics and orthotics were separated, some members stated their vote would not change. For members who voted *no*, the facilitators asked the meaning of qualified PT/OT in terms of statutory construction from their viewpoint. The response was, "it means required education, training, and experience above what they currently have. For example, Certified Hand Therapists (CHTs) have specialty training."

Dr. Hill emphasized to the group that the committee may need to force consensus for the law to be written. Otherwise, he explained, CMS would write something they like, write something they don't like, or write something that won't be passed into law.

- Q: Are OTs primarily concerned with orthotic MTPM and are PTs primarily concerned with immediate post-op prostheses?
- A: OTs do not view this rule as a way to expand our practice. There are people who seek necessary education by virtue of practice and ethical rules. There is no need for more certification.
- A: The PT concern is practice as a qualified provider under Medicare.

The suggestion to have a caucus on this issue was enacted. After the caucus, the facilitators informed the group that headway had been made on the issue. Before adjourning for the day, Ms. Sylvester listed a number of options for the committee to consider overnight. While considering the options, she asked the committee to come up with creative solutions to bridge the gap towards consensus on the issue of qualification and to look at the list of L codes provided by Joel Kaiser as homework.

# The options were:

- Consensus on a rule everyone can live with
- CMS writes rule you don't like
- CMS writes rule you like
- No regulation continuation of status quo
- Continue meeting forever

The call was made for public comment. There was none. The first day of the meeting was adjourned at 4:50 p.m.

# Day 2 – March 11, 2003

The second day of the Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics meeting began shortly after 8:00 a.m. The first topic to be addressed was for the committee to reach consensus on the preliminary definition of prosthetics covered under the statute. The group agreed to following preliminary definition:

All external upper and lower prostheses are covered by the statute. These include existing codes L5000 - L7520, L8400 - L8499, K0556 - K0559.

Following the vote, Joel Kaiser addressed questions from the committee.

- Q: The impact of the descriptor language—taking away MTPM on a number of items, will impact us here. Have you considered those items that were changed?
- A: At this point, I'm not sure we can go back to the codes we had before. If an item is MTPM we can consider a coding change. We have a generic descriptor now. It would go to the HCPC workgroup and then we would decide if we need to break them out
- Q: We have codes changed after the law went into effect. Why was there a change in terminology?
- A: The HCPC workgroup wasn't aware of the rule so it wasn't something we were concerned with. You have until April to submit a coding request for the 2004 cycle.
- Q: It was my understanding that custom fabricated or MTPM terms were used to confer complexity of the process of patient care procedures. Is complexity a marker for risk to patient?
- A: Precisely.
- Q: We got your list of codes regarding prosthetics yesterday. The high 7000 codes didn't appear on the list. Was this an oversight?
- A: They were left off because they were accessories not prostheses, e.g., batteries.
- Q: Please clarify the criteria used to set pricing for codes.
- A: The law requires that the fees be based on average allowed charges from 1986/87. These fees are update by an annual factor established in the law. For codes added after 1986/87, fees are "gap filled" using retail prices, which are deflated to 1986/87 using consumer price index for all urban consumers and updated by the fee schedule update factors specified in the law.
- Q: Is clinical risk factored into pricing?
- A: No, it's just a total price.

#### Discussion on which Codes to Include on the List.

Following the question and answer session with Mr. Kaiser, the facilitators asked the committee if the 11 base codes on his list represented the correct universe of base codes. This question yielded several responses, noted below.

- Yes, they are part of the universe that can be MTPM.
- Understand that custom fabrication and MTPM are inherently more complex. When a devise is MTPM it is different from when you make it MTP.
- We can use modifiers for when codes are used for an item individually fabricated over a positive model of the patient.

The group agreed by consensus that all 11 base codes provided by CMS via Joel's list should be included on the final list. Further, the committee agreed to defer its discussion on the nine addition to/replacement codes. When asked for additional base L codes that need to be added to the list, a number of codes were suggested. Following is a comprehensive list (items in italic were proposed on the CMS list as well.)

L0100	L0170	L0130	L0452	L0478	L0480	L0482
L0484	L0486	L0550	L0560	L0700	L0710	L0810
L0820	L0830	L1000	L1200	L1300	L1310	L1640
L1680	L1685	L1700	L1710	L1720	L1730	L1834
L1836	L1840	L1844	L1846	L1855	L1858	L1860
L1870	L1904	L1940	L1945	L1950	L1960	L1970
L1980	L1990	L2000	L2010	L2020	L2030	L2036
L2037	L2038	L2039	L2040	L2050	L2060	L2070
L2080	L2090	L2102	L2104	L2106	L2108	L2124
L2126	L2128	L3720	L3730	L3740	L3800	L3805
L3900	L3901	L3902	L3904	L3906	L3907	L3963
L3985	L3986					

When asked for comments to the comprehensive list, the following feedback was given.

- The statute reads "...individually fabricated over a positive model of the patient." We should use this language in our discussions.
- The list (above) contains codes for all custom fabricated orthotics and not "certain" items. NOMA opposes all codes except those on Joel Kaiser's list because we feel the other codes are beyond the scope to the statute.
- All codes require education, training, and experience.
- No item can be included unless the item is individually fabricated over a positive model of the patient. Some codes (above) don't apply.
- Each code listed is individually fabricated and can be made over a positive model of the patient.
- Q: How did you select theses orthotic codes to be on the list? (Asked of Bill DeToro, American Board of Certification)

- A: I can send the spreadsheet to the committee to explain the rationale before the next meeting. But essentially, we had five categories. Terry Supan, State Boards, took the AOPA spreadsheet and then we used the decision tree, then a word search and verified everything. Next we took out items relating to shoes or shoe inserts and then I said in my experience if it's done over a model of the patient then it's on the list. I gave the list to a couple committee members and they modified it as they saw appropriate. These codes are codes where the patient is clinically or economically at risk. I also shared the list with some members of the P/O community.
- Q: Are there any codes on the list that are individually fabricated and not routinely made over a positive model of the patient?
- A: Yes.
- Q: Are there any that have been molded over a model of the patient?
- A: The 1900 series of codes (ankle foot orthoses). Some are made over a molded model. Some, routinely 99% are done over a plaster cast made from an impression of the patient.
- Q: Would we get a code if it were billed and not made over a model in your 99% scenario?
- A: If it's virtual or not it still has to be made over a model.
- Q: What items are more likely, on the list, to be made over a positive model (more than 50% of the time)?
- A: We would have to review the list and come up with that.
- A: In my practice, between 5 to 9% are done with a CAD driven model, the rest are done from cast over a model of the patient for the 1900 series codes.
- A: The majority of the metal ankle foot orthoses (AFOs) are made from a tracing. The 1960 code is made from a mold or shape of the leg. When a low temperature device is made, this is considered different because it is not intended to be permanent.
- Q: At the end of the day do you envision a list of codes? (Asked of CMS)
- A: I'm hoping we can come up with definitions and descriptors so if there are changes in codes we will know the will of the committee.

(Joel Kaiser responded to another series of questions asked by the committee.)

- Q: Joel, is your list done?
- A: The list is not done yet. There are codes that say custom fabricated that include MTPM. At some point in time we have to identify other items that are not on the list. We didn't know the rule was going to say MTPM. It seems to me you would have a MTPM code and then another code for custom fabricated other than MTPM

- Q: Is there any frequency consideration for when something is MTPM?
- A: If it says MTPM it is MTPM, always. Frequency is not considered. That is why we initially had a general code for custom fabricated. Now with this new regulation, we have to distinguish MTPM.
- Q: In looking at the additional codes, to the extent you create a MTPM code, what would you do with pricing for the additional code?
- A: We currently have a fee for custom fabrication. It is all-inclusive. The fee would likely not change if we created a MTPM code. The payment would be the same.
- Q: Would you say it's an acknowledgment of complexity of the process?
- A: No, it's just our policy that payment is based on average of 1986/87 payment.
- Q: So the focus is on the fee base, not complexity?
- A: It's just a fee based on the rule. The fee won't change.
- Q: At the last meeting we concluded that custom fabricated included MTPM among other things. I believe custom fabricated and MTPM are synonymous. Is this your view?
- A: Custom fabrication is a general term.
- Q: Why is code 0486 on your list if it doesn't include MTPM?
- A: It says MTPM in a slightly different way. It says plaster and CAD CAM.
- A: When the term custom fabricated was designed, it included MTPM and other types of custom fabrication. CAD CAM can be molded to patient digital model, so we included it in our coding. (Response from Bonnie Brooks, representing the four regional DMERCs/SADMERC.)
- Q: Would CAD CAM fall under custom fabricated under a TLSO?
- A: This is molded over a digital model of the patient so regardless of how it's molded it still uses a patient model, whether its casting or 3-D.

Dr. Hill told the group CMS would like to have a definition of positive model of the patient as broad as possible within the confines of the law for more patient protection. To that end, he stated, "if we can tell OTs and PTs we accept their definition of "qualified," I hope we can win their approval for a more lengthy (broader) list of codes."

In response to this comment, Michael Brncick from the National Commission on Orthotic and Prosthetic Education stated, "I can't say they are qualified to do the full spectrum of O&P care. They do what they do and we do what we do. We need to talk about the impact this will have on the law. We are concerned what implications this will have down the line. We were more comfortable with have them "demonstrate" competency. Before we can accept them as "qualified" you could do some distance learning as an option. We are not saying PTs/OTs are incompetent. We know there are realms of O&P that they do very well. It's the other areas we are concerned about."

Julie Kass, AOTA, responded by saying, "we have a scope of practice and O&P does also. All O/P can't do halos. So we work within our scope of competency. You are not being asked to "demonstrate" you competency." To this, Mr. Brncick added, "there does not seem to be an issue with qualifications. Maybe we could have a 1-page exam to show competency. There could be other ways to demonstrate competency besides testing also. For example, we could have specialty modules to expand PT/OT areas of expertise."

The group took a caucus to continue discussing this issue.

After the caucus Terry Supan told the group he created subcategories comprising the titles 3-D model, 2-D model, and direct form to patient. He said he would distribute the form to the committee and compile the feedback for the group.

When the facilitators called for public comment, Mr. Ted Kadasy from the Board of Certification for Pedorthics addressed the committee. He provided a handout (Attachment 5.7 – Memorandum) and asked the committee to consider the issue raised in the handout on its next agenda.

Agenda items for the April 7-8 meeting are as follows:

- Barr Question (the facilitators agreed that the Barr question would be the first item on the next agenda)
- Qualified Providers (PTs/OTs)
- L codes and definitions of custom fabrication and individually fabricated over a positive model of the patient
- Qualified supplier issue
- Board of Certified Pedothics (BCP) L code

The facilitators thanked the committee for its hard work and told them they thought the discussions over the course of the last few days were good and the caucuses were effective. They asked each member to consider the goals of their respective groups until the committee met again.

The meeting was adjourned at 3:20 p.m.

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# **List of Attachments**

Attachment 5.1	Sign-in Sheet
Attachment 5.2	Rolling Agenda
Attachment 5.3	Meeting #4 Minutes
Attachment 5.4	BIPA427 Codes (from Joel Kaiser)
Attachment 5.5	PT Supporting Document Package
Attachment 5.6	OT Supporting Documents Package
Attachment 5.7	Memorandum (from Ped. Orthotists)
Attachment 5.8	Public Comment Letters

#### M - E - M - O - R - A - N - D - U - M

**TO:** The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics

and Certain Custom-Fabricated Orthotics

**FROM:** The Board for Certification in Pedorthics

**SUBJECT:** Qualified Provider/Supplier Status for BCP Certificants

The Board for Certification in Pedorthics (BCP) appreciates and would like to thank the members of The Negotiated Rulemaking Committee on Special Payment Provisions for Prosthetics and Certain Custom-Fabricated Orthotics (the Committee) for all of your hard work during this process. As observers and members of the public, BCP's representatives at the meetings have been impressed with the thoughtful efforts put in toward finding consensus on a variety of complicated issues.

#### **BCP's Request**

BCP, with the support of the Pedorthic Footwear Association, requests that the Committee include a provision in its rulemaking that BCP be acknowledged by the Secretary of Health and Human Services as a credentialed and approved program whose certificants are deemed 'qualified providers' and 'qualified suppliers' consistent with their Scope of Practice under Sub-section (F)(iii)(III) and (F)(iv) of Section 1834(h)(1) (42 U.S.C.1395m(h)(1)). Certified Pedorthists currently use the following base codes (as well as appropriate addition, repair, and transfer codes):

L1904	Ankle foot orthosis, molded ankle gauntlet, custom-fabricated:		
L2999	Lower extremity orthosis, not otherwise specified		
L5000	Partial foot, shoe insert with longitudinal arch, toe filler		
L5999	Lower extremity prosthesis, not otherwise specified		

#### The Role of BCP

As you may know, BCP serves two primary roles:

- 1. Determining whether individuals and facilities meet national standards for the practice of pedorthics; and,
- 2. Serving as the public's guardian regarding standards and ethics of pedorthic practice.

Pedorthics is the design, manufacture, modification and/or fit of footwear, including shoes, orthoses and foot devices, to prevent or alleviate foot problems caused by disease, congenital defect, overuse or injury. The practice of pedorthics is generally understood to mean working with patients and their footwear to achieve conformity with a doctor's prescription for footwear as part of the patient's treatment. Certification assures the health care professions and the public that a pedorthist is qualified to fabricate and fit prescribed footwear and related devices.

Facility accreditation recognizes that the physical location where pedorthics is practiced includes the necessary staff, records and resources (such as inventory, equipment, fitting rooms and workshops) to perform pedorthic work on premises in a timely fashion. Like certification of individuals, the accreditation of facilities assures the health care professions and the public that the pedorthic institution adheres to specified national standards and that patients will be treated professionally.

#### **The Certified Pedorthist**

In order to become certified, a pedorthist must complete a defined program of study and pass a certifying examination.

Areas of study include the following:

- Patient Management
- Pathology of Diseases
- Anatomy
- Biomechanics
- Foot Orthoses
- Footwear
- Modification of Footwear
- Pedorthic Assessment
- Practice Management

#### Examination includes the following:

#### Domain I: Pedorthic Assessment

This domain includes but is not limited to topics such as: development of appropriate assessments based on clinician's diagnosis and recommendations and patient's prescription; understanding pedorthic problem by obtaining information about chief complaint, present illness, medical and social history, medications, etc.; assessment of patient's feet for pedal disorders using generally accepted visual and manual techniques, including range of motion and muscletesting; among others.

# Domain II: Implementation

This domain includes but is not limited to topics such as: selection of appropriate last, footwear and/or orthotic design, and materials by correlating the properties of shoe components and/or orthotic designs with the patient's condition in order to maximize the effectiveness of pedorthic treatment; for custom-molded foot orthoses and/or partial foot prostheses, create a positive model by securing a negative foot impression using appropriate casting or computer-assisted techniques in order to fabricate the device; and, conducting appropriate follow-up assessments of the efficacy of devices and making adjustments as necessary in order to implement and/or modify the treatment plan; among others.

#### Domain III: Practice Management

This domain includes but is not limited to topics such as: compliance with universal precaution procedures, occupational safety and health rules, and disability accommodation guidelines; proper documentation of patient information in order to ensure quality patient care; maintenance of suitable facilities by ensuring appropriate environment for patient care; and, implementation and compliance with quality assurance programs in order to track deficiencies in operations by reviewing outcomes and addressing issues raised by patients, and referring health care practitioners; among others.

## Domain IV: Professional Development and Responsibility

This domain includes but is not limited to topics such as: adherence to legal and ethical standards and BCP's Standards of Practice; education of the public and health professionals about appropriate use of pedorthic services and the use of conservative foot care management; and, participation in continuing education opportunities in order to improve pedorthic competence; among others.

In order to maintain certification, BCP requires Certified Pedothists to obtain 32 Continuing Education Points (CEPs) over a fixed three-year cycle. Credit is given only for subjects that apply to one of the pedorthic domains and that are within the BCP's current Scope of Practice. Each program session will be judged on the course content, time of contact hours in direct pedorthic education, and speakers who must have the appropriate credentials and be qualified by education and experience to teach their subject matter.

#### **BCP's Standing as a Certification Organization**

BCP should be recognized by the Secretary of Health and Human Services based on its role as the certification organization for pedorthics. BCP is accredited by The National Commission for Certifying Agencies (NCCA), which is the accreditation body of NOCA (National Organization for Competency Assurance). Organizations may apply and be accredited by the NCCA if they demonstrate compliance with each accreditation standard. NCCA is the only national accreditation body for private certification organizations in all disciplines.

NCCA accredits certification entities that are national in scope using standards developed originally in 1978 with seed money provided by the U.S. Department of Health and Human Services. The standards have recently been updated through a careful review process. NCCA has been and continues to be active in accrediting a variety of certification programs.

The accreditation process includes an intensive review of certification entity documents and examination material (validation studies, reports, etc.) used in the agency's certification activity. Once achieved, accreditation is maintained through an annual reporting cycle and re-application every five years.

BCP was first accredited by NCCA in 1984 and continues to meet all requirements necessary to maintain NCCA accreditation.